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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/007,790

11/13/2001

Yasuhisa Fukui

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21874

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02/13/2004

EDWARDS & ANGELL, LLP

P.O. BOX 55874

BOSTON, MA 02205

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

1

**Office Action Summary**

Application No.

10/007,790

Applicant(s)

FUKUI ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-21 and 27 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-21 ~~is/are~~ are allowed.
- 6) ☒ Claim(s) 27 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 94,624, 63, 215
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 10/29/03 in response to the non-final Office Action mailed 07/29/03. With this, Applicants have amended the specification.

### **Status of Claims**

- 2) Claims 18-21 have been amended via the amendment filed 10/29/03.  
Claims 22-26 have been canceled via the amendment filed 10/29/03.  
New claim 27 has been added via the amendment filed 10/29/03.  
Claims 18-21 and 27 are pending and are under examination

### **Objection(s)**

- 3) The objection to the drawings made in paragraph 6 of the Office Action mailed 07/29/03 under 37 C.F.R 1.84 is withdrawn in light of Applicants' submission of formal drawings.
- 4) The objection to the specification made in paragraph 7 of the Office Action mailed 07/29/03 is withdrawn in light of Applicants' amendments to the specification.
- 5) The objection to claim 18 made in paragraph 9 of the Office Action mailed 07/29/03 is withdrawn in light of Applicants' amendment to the claim.

### **Specification: Sequence Non-compliance**

- 6) The amino acid sequence(s) recited in Figure 8 contain more than four amino acids, yet are not identified by a SEQ ID NO. either in the Figure 8 drawing or in the description for Figure 8 as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANTS MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

### **Rejection(s) Withdrawn**

- 7) The rejection of claim 18 made in paragraph 8(a) of the Office Action mailed 07/29/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn.
- 8) The rejection of claim 19 made in paragraph 8(b) of the Office Action mailed 07/29/03

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under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

9) The rejection of claim 18 made in paragraph 8(c) of the Office Action mailed 07/29/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claim 20 made in paragraph 8(d) of the Office Action mailed 07/29/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 21 made in paragraph 8(e) of the Office Action mailed 07/29/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claim 20 made in paragraph 8(f) of the Office Action mailed 07/29/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claim 18 made in paragraph 8(g) of the Office Action mailed 07/29/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

#### **Rejections under 35 U.S.C. § 112, Second Paragraph**

14) Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 27 lacks proper antecedent basis for the recitations: 'variable region thereof' and 'an antigenic determinant'. Since both the limitations have been recited earlier in the same claim or the claim from which the instant claim depends, it is suggested that Applicants replace the limitations with --the variable region thereof-- and --the antigenic determinant--.

(b) Claim 27 is confusing and/or lacks proper antecedent basis in the recitation: 'a sample' (see last line). Claim 27 depends from claim 18, which already recites 'a sample'. Is 'a sample' recited in claim 27 different from the sample recited in claim 18?

(c) Claim 27 is confusing. Claim 21 depends from claim 18, which is drawn to a method which includes two steps: a) reacting a sample containing phosphatidylinositol-3,4,5-triphosphate with a specific monoclonal antibody or a variable region thereof; and b) detecting the immunological binding or reaction between the monoclonal antibody or the variable region and a specific antigenic determinant on

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phosphatidylinositol-3,4,5-triphosphate present in the sample. Claim 21 recites that the method of claim 18 further comprises the step of c): observing the degree to which the immunological reaction between the two components 'is inhibited by phosphatidylinositol-3,4,5-triphosphate in sample'. It is unclear how, in the same assay, the phosphatidylinositol-3,4,5-triphosphate 'present in the sample' can take part in both binding and inhibition, and how such two processes are measured and/or interpreted. It is not clear how the phosphatidylinositol-3,4,5-triphosphate 'present in the sample' can act both as a binding agent and an inhibitory agent.

#### Remarks

15) Claim 27 stands rejected. Claims 18-21 are allowable once the application becomes sequence compliant.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February, 2004

  
S. DEVI, PH.D.  
PRIMARY EXAMINER